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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/536,822

10/18/2005

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0666.2510000/TGD/AFK

6627

26111 7590 03/20/2008
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EXAMINER

BERTAGNA, ANGELA MARIE

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

03/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/536,822	Applicant(s) HIRAI ET AL.	
	Examiner ANGELA BERTAGNA	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/27/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-4, in the reply filed on December 12, 2007 is acknowledged.

Claims 5-7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on December 12, 2007.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

3. Applicant's submission of an Information Disclosure Statement on May 27, 2005 is acknowledged. A signed copy is enclosed.

Claim Rejections - 35 USC § 112, 2nd paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 are indefinite, because the recitation of the phrase “characterized in that” appearing in these claims causes the scope of the claims to be unclear. Substitution of "wherein" for "characterized in that" should overcome this rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorelov et al. (Physica A (1998) 249(1): 216-225).

These claims are drawn to a method for concentrating and purifying a nucleic acid using electrophoresis. In the method, a nucleic acid-containing sample is subjected to electrophoresis in the presence of a cationic surfactant, which adjusts the electric charge of an impurity present in the sample, thereby permitting electrophoretic separation of the nucleic acid from the impurity.

Gorelov studied the interaction between DNA and a cationic surfactant (see abstract and pages 217-220). Regarding claims 1 and 2, Gorelov teaches incubating a DNA sample with a cationic surfactant and performing capillary electrophoresis, thereby purifying and concentrating the nucleic acids in the sample (see section 2.1 on page 217, section 2.4 on pages 219-220, and Figure 2). Gorelov further teaches that the cationic surfactant interacts with the DNA in the sample by displacing positively charged bound counterions (see pages 223-224). Thus, the inclusion of the cationic surfactant adjusted the electric charge of the previously bound counterions as required by the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gorelov et al. (Physica A (1998) 249(1): 216-225) in view of Irie et al. (US 6,387,235 B1).

Claim 3 is drawn to a method for concentrating and purifying a nucleic acid using electrophoresis. In the method, a nucleic acid-containing sample is subjected to electrophoresis in the presence of a cationic surfactant and a nonionic surfactant, which adjust the electric charge of an impurity present in the sample, thereby permitting electrophoretic separation of the nucleic acid from the impurity.

Gorelov studied the interaction between DNA and a cationic surfactant (see abstract and pages 217-220). Regarding claim 3, Gorelov teaches incubating a DNA sample with a cationic surfactant and performing capillary electrophoresis, thereby purifying and concentrating the nucleic acids in the sample (see section 2.1 on page 217, section 2.4 on pages 219-220, and Figure 2). Gorelov further teaches that the cationic surfactant interacts with the DNA in the sample by displacing positively charged bound counterions (see pages 223-224). Thus, the inclusion of the cationic surfactant adjusted the electric charge of the previously bound counterions.

Gorelov does not teach further adding a nonionic surfactant with the cationic surfactant.

Irie teaches a method and apparatus for separating DNA molecules by capillary electrophoresis (see abstract and column 4, line 59 – column 6, line 59). Regarding claim 3, Irie teaches that the electrophoresis buffer includes the nonionic surfactant Tween 20 to prevent adsorption of the DNA molecules in the detection chamber (column 9, lines 26-34).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to further include a nonionic surfactant when performing the method taught by

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Gorelov. An ordinary artisan would have been motivated to do so, since Irie taught that inclusion of a nonionic surfactant minimized undesirable DNA adsorption during the detection step (see column 9, lines 26-34). Since both Gorelov and Irie used capillary electrophoresis to separate and purify nucleic acids, an ordinary artisan would have had a reasonable expectation of success in including a nonionic surfactant in the method of Gorelov as suggested by Irie. Thus, the method of claim 3 is *prima facie* obvious over Gorelov in view of Irie in the absence of secondary considerations.

8. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon, III et al. (US 6,129,828; cited previously) in view of Asai (US 6,165,758).

These claims are drawn to a method for concentrating and purifying a nucleic acid using electrophoresis and at least one surfactant. In the method of claims 1 and 2, a nucleic acid-containing sample is subjected to electrophoresis in the presence of a cationic surfactant, which adjusts the electric charge of an impurity present in the sample, thereby permitting electrophoretic separation of the nucleic acid from the impurity. In the method of claims 3 and 4, the cationic surfactant adsorbs to an impurity in the sample, thereby permitting purification of the nucleic acid from the impurity. The method of claims 3 and 4 further includes a nonionic surfactant whose concentration is adjusted to control to adsorption of the cationic surfactant to the impurity.

Sheldon teaches a method for concentrating and purifying nucleic acids using electrophoresis (see abstract and column 5, line 60 - column 6, line 59). The method of Sheldon separates nucleic acids from impurities using affinity or mobility-based methods (see column 6,

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lines 2-7 and lines 28-59; see also column 9, line 59 - column 10, line 13). Sheldon teaches that the charge or electrophoretic mobility of contaminants (*e.g.* proteins present in a crude cell lysate) can be altered to permit their separation from the desired nucleic acids (see column 9, line 59 – column 10, line 13).

Sheldon further teaches that protein traps comprising PVDF, nitrocellulose, hydrophobic materials, negatively charged materials, or positively charged materials can be used to remove protein impurities from the nucleic acid-containing sample (column 12, lines 47-55). Sheldon teaches that these traps can further include detergents or surfactants (column 12, lines 53-58), but does not expressly teach using the surfactant to modify the charge of an impurity in the sample.

Asai teaches a method for separating an enzyme (CC acylase) from a contaminant protein (deacetylase) that comprises adding a cationic surfactant to the sample to selectively aggregate and precipitate the deacetylase contaminant (see abstract and column 2, lines 20-42; see also Example 1 and Table 1 at columns 5-6). Asai teaches that the deacetylase contaminant could not be removed by conventional means since its chromatographic behavior is essentially identical to that of CC acylase (column 1, lines 42-64). Asai also teaches that non-ionic surfactant could be used to achieve the same purpose (see Example 1 and Table 1 at columns 5-6).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to apply the teachings of Asai to the method taught by Sheldon. Since Asai taught that cationic or nonionic surfactants could be used to aggregate and remove a protein contaminant (see column 2, lines 20-42 and Example 1 at columns 5-6), an ordinary artisan would have been motivated to use a cationic or nonionic surfactant in the method of Sheldon to trap, and thereby, alter the electric charge of protein contaminants, thus permitting electrophoretic separation of the

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desired DNA molecules. An ordinary artisan would have been further motivated to use a mixture of cationic and nonionic surfactant in the method taught by Sheldon, since Asai taught that both types of surfactant were useful for aggregating and precipitating contaminating proteins (see Table 1 in column 6). As noted in MPEP 2144.06, "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)." Finally, regarding claim 4, attention is directed to MPEP 2144.05, which states, "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. '[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.' In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)." In this case, an ordinary artisan would have recognized that the surfactant concentrations were results-effective variables that should be optimized in order to maximize removal of protein contaminants without hindering nucleic acid separation. Thus, optimization of the cationic and nonionic surfactant concentration is *prima facie* obvious in the absence of secondary considerations.

Double Patenting

9. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v.*

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Eagle Mfg. Co., 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

10. Claims 1-4 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4 of copending Application No. 10/578,770. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-4 are directed to the same invention as that of claims 1-4 of commonly assigned application 10/578,770. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Conclusion

11. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amb

/Cynthia Wilder/
Patent Examiner, Art Unit 1637